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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,515

11/06/2003

Said I. Hakky

MR2493-38

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06/09/2006

ROSENBERG, KLEIN & LEE
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ELLICOTT CITY, MD 21043

EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/701,515

Applicant(s)

HAKKY ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it exceeds 150 words in length.

Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 1 is objected to because of the following informalities: at line 18, after “mechanism” replace “do” with --does--. Appropriate correction is required.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 4-6 are based on an embodiment that combines a wire control device mechanism as shown in figures 2-3B with a balloon mechanism as shown in figures 4 and 5. There is no support in the figures, specification or any previously pending claim for this embodiment.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 7, 8 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Termanini (US 4,154,242).

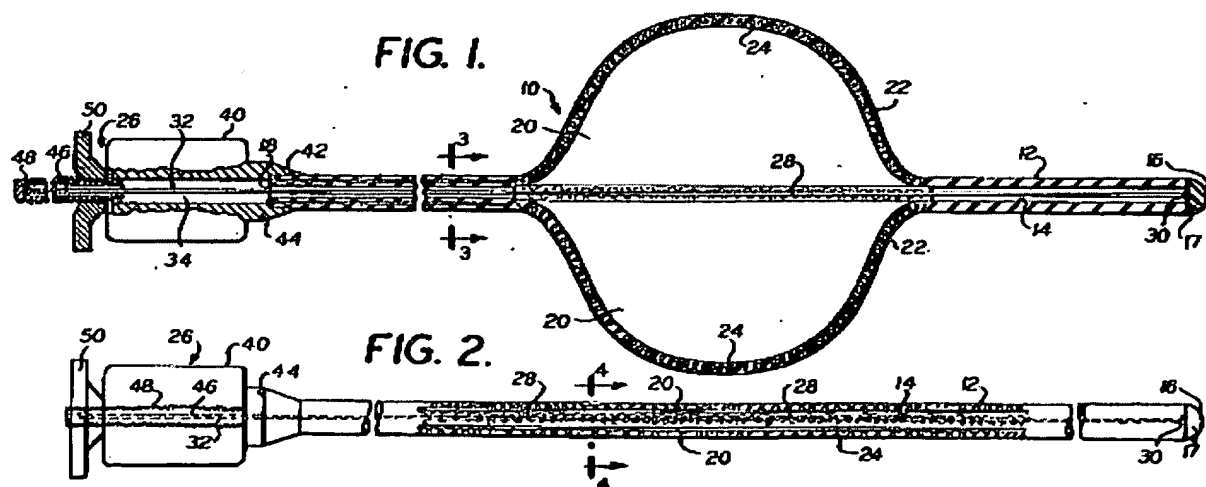
Regarding claim 1, Termanini teaches a self-retaining urinary drainage catheter system (10), comprising:

(a) a longitudinally extending flexible tube (12) having a predetermined outer diameter, an open distal end (18) and a closed proximal end, said flexible tube (12) defining at least one lumen (14), said closed proximal end having a plurality of longitudinally directed slits (20) formed through a wall of said flexible tube (12) defining a plurality of flexible tube (12) slit portions (24); and

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(b) a reversibly and radially displaceable mechanism for displacing said plurality of flexible tube slit portions (24) of said proximal end to a first configuration (fig. 1) abutting in a non-continuous manner an inner surface of a urinary bladder, said first configuration of flexible tube slit portions (24) having an outer diameter greater than said predetermined diameter of said flexible tube (12) and defining a plurality of drainage apertures (20), and for displacing said plurality of flexible tube slit portions (24) to a second configuration (fig. 2) wherein said plurality of flexible tube slit portions (24) has a diameter substantially equal to said predetermined outer diameter of said flexible tube (12), said plurality of drainage apertures (20) being in direct fluid communication with said lumen (14), wherein said reversibly and radially displaceable mechanism (24) does not substantially obstruct a lumen (24) of said catheter (10), and said catheter (10) is reversibly insertable in a human being without using a stylet; and

(c) a wire control device (28) positionally located external and displaced from the longitudinally extending flexible tube (12), said wire control device (28) having a reversible locking mechanism (48, 50) for locking said wire control device (28) in a predetermined position (se figures 1 & 2, infra).



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Regarding the functional limitations (e.g., reversibly insertable), apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114.

Termanini does not expressly teach that the catheter has a sufficient stiffness to be reversably inserted into a human without using a stylet. Termanini, in describing the deficiencies of the prior art, cites the problems concerning using a stylet to insert a catheter (col. 2, line 57- col. 3, line 12). Termanini describes inserting a catheter without mention of a stylet. Considering the disclosure of Termanini as a whole, it is clear that Termanini implies that the disclosed catheter does not require a stylet for insertion and that accordingly, the catheter is sufficiently stiff to allow for such insertion.

Regarding claims 2 and 8, Termanini teaches that said a wire control device (28) is longitudinally and slidably positioned within a lumen (14) of said longitudinally extending flexible tube (12), said wire control device (28) fixedly secured at a first end (30) to an inner surface of said closed proximal end (16) and having a length greater than a length of said longitudinally extending flexible tube (12) so that a second end of said wire control device (28) protrudes through said open distal end (18)(figures 1 and 2).

Regarding claim 7, Termanini teaches that the wire control device (28) is composed of a metal or non-metallic material (nylon, polypropylene)(column 4, lines 43-47).

Regarding claim 12, Termanini teaches that said wire control (28) device further comprises a means (48, 50) for reversibly locking said wire control device (28) in a predetermined position (figures 1 & 2).

Claims 9-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Baskin (US 2,854,983) in view of Rosenberg (US 4,787,892).

Regarding claim 9, Baskin teaches a self-retaining urinary drainage catheter system (10), comprising:

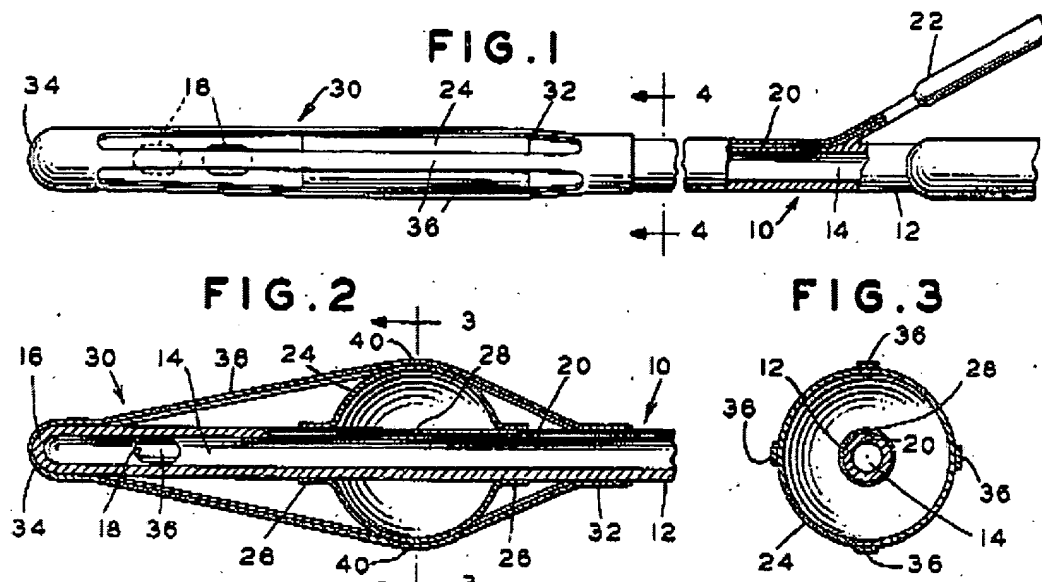
(a) a longitudinally extending flexible tube (12, 30) having a predetermined outer diameter, an open distal end and a closed proximal end (34), said flexible tube (12, 30) defining at least one lumen (interior of tubular element (30)), said closed proximal end (34) having a plurality of longitudinally directed slits (36) formed through an outer wall of said flexible tube (12, 30) defining a plurality of flexible tube slit portions (36); and

(b) a reversably inflatable balloon (24) located between said plurality of flexible tube slit portions (36), a microcatheter (20), wherein a fluid may be reversably injected so as to expand said reversably inflatable balloon (24) for reversably and radially displacing said plurality of flexible tube slit portions (36) of said proximal end (34) to a first configuration abutting in a non-continuous manner an inner surface of a urinary bladder, said first configuration of flexible tube slit portions (36) having an outer diameter greater than said predetermined diameter of said flexible tube (12, 30) and defining a plurality of drainage apertures (36), and displacing said plurality of flexible tube slit portions (36) to a second configuration wherein said plurality of flexible tube slit portions (36) has a diameter substantially equal to said predetermined outer diameter of said flexible tube, said plurality of drainage apertures being in direct fluid communication with said lumen wherein said microcatheter (20) does not substantially obstruct a lumen of said catheter (10), and said catheter (10) being of sufficient stiffness to be reversably insertable in a human being without using a stylet (see figures 1 and 2, below).

Regarding the functional limitations (e.g., reversibly insertable), apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114. The device of Baskin could be

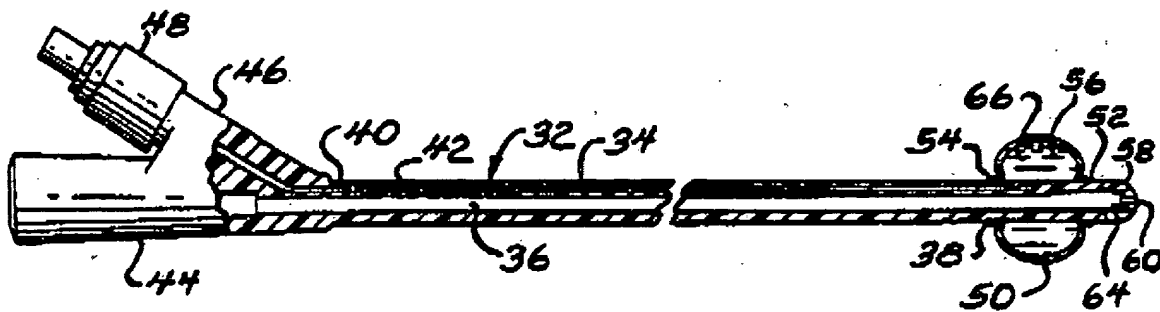
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at least be partially inserted into a sufficiently large diameter wound or human orifice without the aid of a stylet.



Baskin does not expressly disclose a valve.

Rosenberg teaches a balloon catheter (32) having a balloon inflation tube (42) that controls fluid flow to the balloon via a valve (48)(see figure 6, below).



At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the valve of Rosenberg to the fluid inflation tube of the catheter of Baskin in order to provide a means of keeping the balloon inflated.

Regarding claim 10, Baskin teaches a spherical balloon (24)(figure 2).

Regarding claim 11, Rosenberg teaches an oblong balloon (50)(figure 6).

Response to Arguments

Applicant's arguments filed 04 April 2006 have been fully considered but they are not persuasive.

Regarding claims 9-11, applicants assert that Baskin and/or Rosenberg fail to teach a plurality of apertures in direct fluid communication with the lumen. This argument is not persuasive because as interpreted herein, in the reference to Baskin, the slits between elements (36) are considered the apertures and the interior of tubular element (30) is considered to be the lumen.

Applicants assert that the device of Rosenberg requires a stylet during use. This argument is not persuasive because the relevant limitation of the instant invention is functional. The combination of Baskin and Rosenberg can be used in the claimed manner (see detailed rejection, supra).

Applicant's arguments with respect to claims 1, 2, 4-8 and 12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart

1 June 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

